

**2009 H1N1 Influenza
Updated Key Points
December 24, 2009**

What's New and Updated

- Activity Update
- 2009 H1N1 Influenza Vaccine
- 2009 H1N1 Influenza Vaccine Safety
- Seasonal Influenza Vaccine

A Summary of CDC Key Public Health Messages this Season

- Flu activity continued to decline in the United States during the week of December 13-19, 2009, as reported in [FluView](#). The number of states reporting widespread flu activity decreased from 11 to 7. Visits to doctors for influenza-like illness, flu-associated hospitalizations, and flu-associated deaths all declined from the previous week.
- Flu activity is expected to continue for months, caused by either 2009 H1N1 viruses or regular seasonal flu viruses, although levels of activity are expected to vary during the season.
- CDC recommends a three-step approach to fighting the flu:
 - vaccination;
 - everyday preventive actions, including covering coughs and sneezes, frequent hand washing, and staying home when sick;
 - and the correct use of antiviral drugs if your doctor recommends them.
- There is no way to accurately predict the course of influenza epidemics. Right now is a window of opportunity for more people to get vaccinated for 2009 H1N1 flu. Supplies of 2009 H1N1 vaccine are increasing and many places have opened up vaccination to anyone who wants it.
- It's very important that antiviral drugs be used early to treat flu in people who are very sick (for example people who are in the hospital) and people who are sick with flu and have a greater chance of getting serious flu complications, like people with asthma or diabetes or women who are pregnant.

Activity Update

- Each week CDC analyzes information about influenza disease activity in the United States and publishes findings of key flu indicators in a report called FluView.
- Information collected during the week of December 13-19, 2009, is being reported in FluView on December 24, 2009.
- Below is a summary of the most recent key indicators:

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- Visits to doctors for influenza-like illness (ILI) nationally decreased slightly again this week over last week. This is the eighth consecutive week of national decreases in ILI after four consecutive weeks of sharp increases. Nationally, visits to doctors for influenza-like illness remain slightly elevated.
- Influenza hospitalizations and hospitalization rates decreased in all age groups.
- The proportion of deaths attributed to pneumonia and influenza (P&I) based on the 122 Cities Report decreased over the previous week. This is the first time in 11 weeks that this proportion has been below the epidemic threshold. (The epidemic threshold is the point at which the observed proportion of deaths attributed to pneumonia or influenza is significantly higher than would be expected at that time of the year in the absence of substantial influenza-related mortality.)
- In addition, nine flu-related pediatric deaths were reported this week: eight of these deaths were associated with laboratory confirmed 2009 H1N1, and one was associated with an influenza A virus that was not subtyped.
- Since April 2009, CDC has received reports of 285 laboratory-confirmed pediatric deaths: 241 due to 2009 H1N1, 42 pediatric deaths that were laboratory confirmed as influenza, but the flu virus subtype was not determined, and two pediatric deaths that were associated with seasonal influenza viruses. Laboratory-confirmed deaths are thought to represent an undercount of the actual number. CDC has provided estimates about the number of 2009 H1N1 cases and related hospitalizations and deaths
- A table showing reports of flu-related pediatric deaths (including a cumulative total of 2009 H1N1 pediatric deaths since April, 2009) is available on the CDC website at <http://www.cdc.gov/h1n1flu/updates/us/#pedh1n1cases> .
- Since CDC began tracking pediatric flu-related deaths in 2003-2004, the number of pediatric deaths reported to CDC has ranged from 46 during the 2005-2006 season to the 221 deaths reported so far during the 2009-2010 season.
- Seven states are reporting widespread influenza activity; a decline of four states from last week. They are: Alabama, California, Delaware, Maine, Nevada, New Jersey, and Virginia. Eighteen states are reporting regional influenza activity and 13 states and the District of Columbia and Puerto Rico are reporting local influenza activity.
- Almost all of the influenza viruses identified so far continue to be 2009 H1N1 influenza A viruses.

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- These viruses remain similar to the virus chosen for the 2009 H1N1 vaccine, and remain susceptible to the antiviral drugs oseltamivir and zanamivir with rare exception.
 - This week CDC has reported a cumulative 46 cases of oseltamivir resistant 2009 H1N1 viruses in the United States, including 2 newly identified cases since last week.

2009 H1N1 Influenza Vaccine

In this Section:

- Announcements
- Supply
- Recommendations
- Flu Activity Occurs in Waves

Announcements

- **(New)** As part of its quality assurance program, the manufacturer of the nasal spray 2009 H1N1 flu vaccine, MedImmune, performs routine, ongoing stability testing of its influenza vaccine after the vaccine has been shipped to providers. Stability testing means measuring the strength (also called potency) of a vaccine over time. It is performed because sometimes the strength of a flu vaccine can go down over time. On December 18, the manufacturer notified CDC and FDA that the potency in thirteen batches (called "lots") of nasal spray vaccine that had been distributed were later found to have dropped just below a pre-specified limit. The slight decrease in potency should not have any impact on vaccine efficacy. However, the manufacturer will send providers directions for returning any unused vaccine from these lots.
- **(Updated)** As part of its quality assurance program, Sanofi Pasteur performs routine, ongoing stability testing of its 2009 H1N1 flu vaccine after the vaccine has been shipped to providers. Stability testing means measuring the strength (also called potency) of a vaccine over time. It is performed because sometimes the strength of a vaccine can be reduced over time. On December 7, Sanofi Pasteur notified CDC and FDA that the potency in one batch (called a "lot") of vaccine in pre-filled pediatric syringes that had been distributed was later found to have dropped below a pre-specified limit. As a result of this finding, Sanofi Pasteur tested additional lots and found that three other lots that had been distributed

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also had an antigen content that, while well within specifications at the time of manufacturing, was later measured to be below pre-specified limits. This means that doses from these four vaccine lots no longer meet the manufacturer's specifications for potency. Sanofi Pasteur has sent providers directions for returning any unused vaccine from these lots.

- **(New)** An article in the December 21, 2009, *Journal of American Medical Association* (JAMA) was released today. "Immunogenicity of a monovalent 2009 Influenza A(H1N1) vaccine in infants and children: a randomized trial" (Nolan et al) describes a study that found that one dose of 2009 H1N1 vaccine stimulated a protective antibody response among most healthy infants and children. CDC has written an editorial in response to this article, which is also available in today's issue.
- **(New)** The editorial summarizes that while most children in the study had an excellent antibody response to one dose, children younger than 10 years of age still had a lower response than older children and adults.
- **(New)** Experience with seasonal flu vaccines shows that young, previously vaccinated children who receive one dose of vaccine are not as well protected from infection as children who have received two doses of vaccine.
- The vaccine for 2009 H1N1 flu will be the same for the entire 2009-2010 influenza season, which extends into the spring of 2010. The "2009" in the name only relates to the year the virus was first identified; it does not have to do with how long the vaccine will work or the year in which it should be administered. The 2009 H1N1 strain is not included in the 2009-2010 seasonal flu vaccine because it was identified after manufacturers had started making the seasonal flu vaccine.
- **(Updated)** Last week marked the first 100 million doses of 2009 H1N1 vaccine available for ordering.
- National Influenza Vaccination Week (NIVW) is a national initiative that was established to highlight the importance of continuing influenza vaccination, as well as to foster greater use of flu vaccine after the holiday season into January and beyond. This year's NIVW, originally scheduled for December 6-12, 2009, is now rescheduled to January 10-16, 2010. Updates will be provided as more information becomes available.
- We hope that all of our partners will plan their own NIVW events and share their plans with us at www.flu.gov and <http://www.cdc.gov/flu/NIVW/form.htm>.

Supply

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- **(Updated)** As of Wednesday, December 23, 2009, a cumulative total of 112,617,800 doses had been made available for ordering since vaccine shipping began. Of those available doses, 89,579,000 doses were injectable (flu shots) and 23,038,800 were LAIV (nasal spray vaccine).
- **(Updated)** As of Tuesday, December 22, 2009, there were a total of 95,514,300 doses ordered.
- **(New)** There is no way to accurately predict the course of influenza epidemics. Right now is a window of opportunity for more people to get vaccinated for 2009 H1N1flu, to provide protection against a possible third wave of disease as more people gain immunity to the 2009 H1N1 virus. Those who have been patiently waiting for their turn to receive the 2009 H1N1 vaccine are now encouraged to get vaccinated.
- The further delivery of Sanofi Pasteur 7.5 microgram prefilled syringes is delayed indefinitely due to release issues at the manufacturer.

Recommendations

- Parents are now encouraged to seek the second dose of 2009 H1N1 vaccine for their children who are younger than 10 years old. The recommended interval between the first and second dose should be at least 28 days; however, a second dose given at least 21 days after the first is considered valid.

Flu Activity May Occur in “Waves”

- The timing, spread and severity of influenza viruses is uncertain.
- Outbreaks of influenza may occur in different places at different times.
- Outbreaks may occur in waves of about 6-12 week time periods.
- These waves of influenza may occur over a year or so after the emergence of a new influenza virus.
- In past pandemics, “waves” of activity have been observed.
- The first wave is usually a smaller wave; followed by a larger “peak” wave. Subsequent smaller waves can occur as well.
- The United States experienced its first wave of 2009 H1N1 pandemic activity in the spring of 2009.
- At this time, we are experiencing a second wave of 2009 H1N1 activity.
- It’s possible that other waves of influenza activity may occur after this current wave – caused by either 2009 H1N1 viruses or regular seasonal flu viruses.

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- Because the timing and spread of influenza viruses are unpredictable, CDC is continuing to recommend vaccination with seasonal influenza vaccine and 2009 H1N1 vaccine for those people in whom it is recommended.

2009 H1N1 Influenza Vaccine Safety

- All data coming into CDC's vaccine safety surveillance systems continue to confirm that the 2009 H1N1 vaccine is safe.
- At the same time, CDC, FDA, and our partners, continue to rigorously monitor the safety of H1N1 and seasonal flu vaccines.
- CDC is aware that pregnant women and parents of young children may have questions about the safety of thimerosal in the multi-dose vials of H1N1 influenza vaccine.
- Thimerosal is a mercury-containing preservative that is added to vials of vaccine that contain more than one dose to prevent contamination and growth of potentially harmful bacteria. Such contamination can cause serious local reactions, illness or death. Thimerosal also increases the length of time a vaccine can remain entirely effective, or potent, before it reaches the patient—the time between manufacturing, shipping, and administering.
- Getting the vaccine is much safer than getting H1N1 influenza. Severe illness and possible death can be associated with influenza, and vaccination is the best way to prevent influenza infection and its complications.
- Currently, the following priority groups have been experiencing higher than usual rates of complications from 2009 H1N1 influenza:
 - Healthy young people from birth through age 24
 - Pregnant women
 - Adults 25 to 64 who have underlying medical conditions
- As with seasonal influenza vaccination, some people getting H1N1 vaccine will have mild side effects such as local injection site pain, redness or swelling in the arm where the shot was given or a runny nose and headache after the nasal spray vaccine.
- Some parents may have questions about the use of thimerosal as a preservative. Research shows no link between thimerosal in vaccines and autism, a neurodevelopmental disorder
- **(New)** Some priority groups may not be able to find thimerosal-free H1N1 flu vaccine due to a recent recall of pre-filled, pediatric 0.25ml single-dose syringes by Sanofi Pasteur licensed for children 6-35 months old:
http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm.

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- Getting the vaccine is much safer than getting H1N1 influenza. For more information on the H1N1 influenza nasal spray vaccine, see <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-laiv-h1n1.pdf>. For more information on the H1N1 influenza shot, see <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-inact-h1n1.pdf>.

In this Section:

Seasonal Influenza Vaccine

Seasonal Influenza Vaccine

- Two systems that look at seasonal influenza vaccinations administered and billed show that more individuals have been vaccinated with seasonal vaccine this season than at the same time last year. This is most likely due to the early availability of vaccine and public interest in getting vaccinated.
- Due to early availability and high demand of seasonal flu vaccine, limited amounts of seasonal supply remain. At this point, CDC continues to encourage those at highest risk from flu complications to seek seasonal flu vaccine and receive 2009 H1N1 vaccine, as recommended.
- **(New)** Two weeks ago, approximately 110 million doses of vaccine had been distributed (96% of the doses expected this season). Since then, even more doses have been shipped. By now it's likely that the total estimated amount of 114 million doses of seasonal flu vaccine have been distributed.
- Local areas may not have received as much vaccine as they anticipated at this point in the season and providers seeking additional vaccine now may be unable to purchase it. For more information about seasonal supply, please refer to IVATS (<http://www.preventinfluenza.org/ivats/>) over the coming weeks.

More information about seasonal flu vaccine supply can be found at:

<http://www.cdc.gov/flu/professionals/vaccination/#supply>